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(54) Title: **CASTING AID AND METHODS OF FORMING CASTS**

(57) Abstract: Casting aids comprising a resin-impermeable substrate and a lubricating material, wherein the lubricating material is coated on at least one surface of said substrate. The casting aid may be used to deliver lubricant as needed to gloves or other surface contacting a tacky resin material during molding or forming of the tacky material. In particular, the lubricant-impregnated porous substrate may be used to lubricate gloves during molding and forming of orthopedic casting materials. The casting may be packaged as a kit with an orthopedic casting material.

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CASTING AID AND METHODS OF FORMING CASTS

BACKGROUND OF THE INVENTION

[0001] The present invention relates to novel aids for use in forming orthopedic casts and other structures made of tacky resinous materials. In particular, this invention relates to flexible resin-impermeable sheets that are coated with a lubricant. In a preferred application, the invention also provides methods for on-demand lubrication of gloves during the formation of orthopedic casts made using tacky resinous materials.

[0002] A wide variety of polyurethane, epoxy and other resins are known in the art for use in forming solid and semi-solid articles. In many instances it is necessary or desirable to form or mold such articles by hand. The resinous material may have a resinous matrix that may be filled with other materials, or may be a resin impregnated into a porous substrate. Practical uses of such materials include knitted or woven fabrics made of fiberglass or other materials impregnated with a tacky material that may be used to repair water pipes or boats, tacky epoxy materials that may be used in repairing mufflers and automobile bodies, and tacky epoxy resin wraps that may be used to repair poles such as utility poles.

[0003] Another area in which resinous materials are used, in particular, is in the formation of casts and splints for immobilizing a body member. Such casts and splints are used, for example, to protect a body part from injury, or to allow a broken bone to heal properly. Historically, such casts were made of plaster of paris. However, plaster casts have recently been largely replaced in many applications by orthopedic bandages or sheets impregnated with tacky synthetic resin mixtures. The synthetic resins used in combination with certain knitted or woven substrates offer a number of advantages over the old plaster materials. In particular, casts made from the synthetic materials are lighter, stronger, harden more quickly, allow for better air circulation, and are not water sensitive.

[0004] Among the synthetic resin compositions used to prepare casting materials are water-activated or water-curable synthetic resin

compositions and thermoplastic resin compositions. Like the old plaster casting material, the water-activated or water-curable synthetic resin impregnated bandages or sheets, which may also be called tapes, are wetted before application to the body member. The water begins the curing reaction 5 that hardens the cast. Other compositions for casting materials use synthetic resin compositions employing different kinds of curing mechanisms, for example crosslinking through unsaturation.

10 [0005] Gloves are often worn while molding such articles by hand, for aesthetic and safety concerns, so as to avoid direct contact of the skin with the resinous material. However, problems may arise due to the inherent tackiness of the resinous materials. For example, in applications involving resin-impregnated fabrics, tackiness of the resin may make it difficult to properly position the fabrics, or to smooth the fabric once in place. A variety of methods have been described in the art to address this problem.

15 [0006] For example, addition of lubricants or other materials to make the resin-impregnated casting sheets slippery is described in U.S. Patent 4,667,661 Scholz et al., issued May 26, 1987, and U.S. Patent 4,774,937 Scholz et al., issued October 4, 1988. The surface of such sheets is said to have a "kinetic coefficient of friction" of less than 1.2. Other casting 20 tapes having a lubricant are disclosed in U.S. Patent 4,937,146, Dull et al., issued June 26, 1990.

25 [0007] Alternatively, various means of delivering a lubricant to a glove used in forming the cast have been suggested. A mixture of water, sorbitol, mineral oil, and silicone fluid is commercially available from 3M Co., St. Paul, Minnesota, under the tradename Cast Cream. This product is applied to the gloves after wrapping, but before molding, the cast. Lubricated gloves are disclosed in European Patent Publication 712,618, Richard et al., published May 22, 1988; U.S. Patent 5,438,709, Green et al., issued August 8, 1985; and U.S. Patent 5,439,439, Green et al., issued August 8, 1995.

30 [0008] Other approaches are described in WO 94/23769, Scholz et al., which describes casting sheets separated by a water-soluble liner layer, which may include a lubricant. Porous sheets impregnated with a lubricant,

which is then rubbed on the surface of a glove, are described in U.S. Patent 5,925,004, Doubleday et al., issued July 20, 1999.

[0009] However, such lubricating methods known in the art have disadvantages. In particular, methods involving pre-lubricated gloves or 5 casting sheets offer no control over the amount of lubricant applied to the gloves, or when it is applied. More lubricant may be applied than is necessary or desirable. For example, it may be desirable to use some sheets with little or no lubricant, so as to have the wrapped layers stick to one another without slipping and to have the end of the sheet or bandage stick to 10 the surface of the casting sheet wrap in order to terminate the application of the sheet. Moreover, incorporating certain lubricants, such as mineral oil, into the curable resin composition may result in longer set time due to the dilution of the resin curing sites. It is also preferable to avoid the transfer of lubricant to the casting resin during storage.

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SUMMARY OF THE INVENTION

[00010] The present invention provides improved methods and articles for delivering a desired amount of lubricant to selected sites on the gloves one or more times when working with tacky materials, in particular tacky resins and polymers. Such methods and articles include, in particular, 20 casting aids and methods for making resinous orthopedic casts. Such casting aids comprise a resin-impermeable substrate, and a lubricating material, wherein said lubricating material is coated on at least one surface of said substrate. Preferably, the substrate is a non-porous flexible sheet comprising a thermoplastic polymer, such as polyester. The lubricating material is 25 preferably a hydrophilic or water-soluble polymer, such as polyvinylpyrrolidone.

[00011] The present invention also provides kits and methods for the formation of an orthopedic cast. Kits comprise a casting material and a casting aid comprising a resin-impermeable substrate and a lubricating 30 material coated on a surface of said substrate. Methods use a casting material, a casting aid, and a glove, and comprise the steps of:

- (1) transferring the lubricating material to a surface of the glove;

- (2) applying the casting material to a body member using the glove; and
- (3) allowing the casting material to harden to form an orthopedic cast.

5 [00012] Applicants have found that the methods and articles of this invention provide benefits versus methods and articles among those in the art. Such benefits include enhanced lubrication, control of the amount of lubricant delivered, control over the time of lubricant use, and control or elimination of the exposure of the resin to lubricant when the casting aid is
10 packaged with the resin material.

DETAILED DESCRIPTION

15 [00013] The invention provides an article that is a resin-impermeable substrate coated with a lubricant. The coated substrate is used to lubricate a glove or other resin handling article (herein referred to as a "glove") before handling tacky resin materials, so that the tacky material may be worked with and formed without sticking to the glove. Articles made using such tacky resin materials (herein "resinous articles") include any of a wide variety of articles which are formed in whole or in part by the application of a resin to a substrate or form. A preferred resinous article is an orthopedic cast.
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25 [00014] As referred to herein, an "orthopedic cast" is a device which encloses, in whole or in part, a body member (e.g., a leg) of a human or other animal subject. Such casts may be flexible, semi-rigid, or rigid, and may be used for the prevention of injury, or in the treatment of disorders such as broken bones. Specific compounds, compositions and other components to be used in such orthopedic casts must, accordingly, be pharmaceutically and cosmetically acceptable. As used herein, such a "pharmaceutically and cosmetically acceptable" component is one that is suitable for use with humans and/or animals without undue adverse side effects (such as toxicity, irritation, and allergic response) commensurate with a reasonable benefit/risk ratio.
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Casting Aid:

[00015] The present invention provides casting aids comprising a resin-impermeable substrate, and a lubricating material, wherein said lubricating material is coated on at least one surface of said substrate. As referred to herein, a "casting aid" is an article that is useful in the handling of resinous materials, or formation of articles comprising resinous materials. Preferred articles comprising resinous materials include orthopedic casts. (As used herein, the word "include" is intended to be non-limiting, such that items that are included in a list are not to the exclusion of other like items that may be useful in the compositions and methods of this invention.)

10 [00016] As referred to herein, a "resin-impermeable substrate" is a material that is not chemically reactive with, and is substantially impermeable to, the resin with which it is to be used. In embodiments in which the casting aid is packaged with the resinous material, the substrate prevents substantial contact between the resin and the lubricating material 15 that is coated on the substrate.

20 [00017] Preferably, the substrate has at least some flexibility or deformability that aids in depositing the lubricating material on the glove or other article that is to be lubricated. Preferred substrates include non-porous films. The substrate may have a broad range of sizes, but preferred substrates are of a size that is large enough to deliver a sufficient amount of lubricant but small enough to be easily handled. Preferably the substrate is a sheet from about 0.25 mm (1 mil) to about 1.0 mm (4 mil), more preferably about 0.5 mm (2 mil), thick. Preferably the substrate sheet is from about 1 cm (.4 in) to about 50 cm (19.6 in) in length, more preferably from about 3 cm 25 (1.2 in) to about 38 cm (15 in) length, more preferably from about 15 cm (5.9 in) to about 25 cm (9.8) in length. Preferably the substrate sheet is from about 1 cm (0.4 in) to about 50 cm (19.6 in) in width, more preferably from about 2 cm (0.78 in) to about 25 cm (8.8 in) in width, more preferably from about 5 cm (1.8 in) to about 13 cm (5.1 in) in width. The substrate may be an 30 individual sheet, or may be in the form of a continuous web of sheets connected in an end-to-end relationship separated by a scored line or perforations, much like paper toweling.

[00018] Preferred substrates are made from a thermoplastic polymer. Preferred polymers include polyolefins, polyesters, polymethylpentene, polyetheretherketone, polyvinyl chloride, polyvinylidene fluoride, polycarbonates, acrylics, and acrylic copolymers, nylon, and mixtures thereof. Particularly preferred polymers include polyesters and polyolefins, particularly polyester high and low density polyethylene and polybutylene. Preferably, polyolefin and polyester films are oxidized using, for example, a high-voltage corona discharge. A preferred substrate comprises polyester. A particularly preferred substrate is a Mylar® polyester film; manufactured by 10 E.I. duPont de Nemours and Company.

[00019] The substrate is coated with a lubricating material. As used herein, "coated" refers to any process by which lubricant material is deposited on or into the surface of the substrate, preferably resulting in a uniform layer of lubricating material, so that lubricating material may be 15 readily transferred to a glove or hand during use.

[00020] Lubricating materials useful herein comprise a lubricant that can be transferred from the substrate to a glove, and that reduces friction between a glove and the resinous article that is to be formed using the glove. Such lubricating materials preferably do not significantly react with the 20 substrate, glove, or resin used to make the resinous article. Lubricants useful in the lubricating materials of this invention include film forming lubricants, preferably film forming hydrophilic polymers. Lubricants useful herein include polyethylene oxide; polyethylene oxide block copolymers such as copolymers of ethylene oxide and propylene oxide; polyvinyl alcohol; hydroxyethyl 25 cellulose; carboxymethyl cellulose; acrylamide-based polymers; polyvinylpyrrolidone; lecithin-based lubricants; sulfonated or carboxylated polymers, such as sulfonated or carboxylated polyurethanes; hydrophilic, oligomeric diols, such as the reaction product of polyethylene oxide glycol with dimethyl sodium sulfoisophthalate in a 2:1 molar ratio; hydrophobic 30 lubricants and oils, such as mineral oils, petrolatum, vegetable oils, and derivatives thereof; synthetic and natural motor oils; silicones and other fluids, oils, and greases, such as polydimethylsiloxanes, polymethylphenylsiloxanes,

and polydiphenylsiloxanes, especially those having viscosities of between about 100 and 100,000 centistokes; fluorinated greases; and mixtures thereof. Preferred lubricants include hydrophilic polymers, such as hydroxyethyl cellulose, carboxy methyl cellulose, polyvinyl alcohol, 5 polyvinylpyrrolidone, polyacrylic acid salts, polyethylene oxide homopolymers and copolymers, and mixtures thereof.

[00021] The lubricating material preferably also comprises a surfactant. Surfactants useful in compositions of the present invention include anionic, nonionic, cationic, zwitterionic and amphoteric surfactants.

10 Anionic surfactants include alkyl and alkyl ether sulfates; the water-soluble salts of organic, sulfuric acid reaction products such as alkali metal and ammonium sulfonated C₁₂₋₁₈ n-paraffins; reaction products of fatty acids esterified with isethionic acid and neutralized with sodium hydroxide where, for example, the fatty acids are derived from coconut oil; sodium or potassium salts of fatty acid amides of methyl tauride in which the fatty acids, for example, are derived from coconut oil; succinamates, such as disodium N-octadecylsulfosuccinamate, tetrasodium N-(1,2-dicarboxyethyl)-N-octadecylsulfosuccinamate, diethyl ester of sodium sulfosuccinic acid, dihexyl ester of sodium sulfosuccinic acid, and dioctyl esters of sodium sulfosuccinic acid; and olefin sulfonates having about 12 to about 24 carbon atoms.

15 Nonionic surfactants include those produced by the condensation of alkylene oxide groups (hydrophilic in nature) with an organic hydrophobic compound, which may be aliphatic or alkyl aromatic in nature. Examples of preferred classes of nonionic surfactants are condensation products of ethylene oxide with the product resulting from the reaction of propylene oxide and ethylene diamine products; condensation products of aliphatic alcohols having from about 8 to about 18 carbon atoms, in either straight chain or branched chain configuration, with ethylene oxide; long chain tertiary amine oxides; long chain tertiary phosphine oxides; and long chain dialkyl sulfoxides containing one 20 short chain alkyl or hydroxy alkyl radical of from about 1 to about 3 carbon atoms (usually methyl) and one long hydrophobic chain which include alkyl, such as octadecyl methyl sulfoxide, 2-ketotridecyl methyl sulfoxide, 3,6,9,-

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triaooctadecyl 2-hydroxyethyl sulfoxide, dodecyl methyl sulfoxide, oleyl 3-hydroxypropyl sulfoxide, tetra decyl methyl sulfoxide, 3-methoxytridecyl methyl sulfoxide, 3-hydroxytridecyl methyl sulfoxide, and 3-hydroxy-4-dodecoxybutyl methyl sulfoxide. Cationic surfactants useful in compositions 5 of the present invention include those comprising amino or quaternary ammonium hydrophilic moieties that are positively charged when dissolved in the aqueous composition of the present invention. Among the quaternary ammonium-containing cationic surfactant materials useful herein are diquaternary ammonium salts, such as tallow propane diammonium 10 dichloride; dialkyldimethyl-ammonium chlorides, wherein the alkyl groups have from about 12 to about 22 carbon atoms and are derived from long-chain fatty acids, such as hydrogenated tallow fatty acid; and salts of primary, secondary and tertiary fatty amines, such as stearamido propyl dimethyl 15 amine, diethyl amino ethyl stearamide, dimethyl stearamine, dimethyl soyamine, soyamine, myristyl amine, tridecyl amine, ethyl stearylamine, N-tallowpropane diamine, ethoxylated (5 moles E.O.) stearylamine, dihydroxy ethyl stearylamine, and arachidyl behenylamine. Zwitterionic surfactants useful herein are exemplified by those which can be broadly described as derivatives of aliphatic quaternary ammonium, phosphonium, and sulfonium 20 compounds, in which the aliphatic radicals can be straight or branched chain, and wherein one of the aliphatic substituents contains from about 8 to about 18 carbon atoms and one contains an anionic water-solubilizing group, e.g., carboxy, sulfonate, sulfate, phosphate, or phosphonate. Other zwitterionics such as betaines are also useful in the present invention. Examples of 25 amphoteric surfactants which can be used in the compositions of the present invention are those which are broadly described as derivatives of aliphatic secondary and tertiary amines in which the aliphatic radical can be straight or branched chain and wherein one of the aliphatic substituents contains from about 8 to about 18 carbon atoms and one contains an anionic water 30 solubilizing group, e.g., carboxy, sulfonate, sulfate, phosphate, or phosphonate. Surfactants among those useful herein are disclosed in the following documents, all incorporated by reference herein: McCutcheon's,

Detergents and Emulsifiers, 1984 Annual, published by Allured Publishing Corporation, Schwartz, et al., Surface Active Agents, Their Chemistry and Technology, New York: Interscience Publishers, 1949; U.S. Patent 3,155,591, Hilfer, issued November 3, 1964; U.S. Patent 3,929,678; Laughlin et al., 5 issued December 30, 1975; U.S. Patent 3,959,461, Bailey et al., issued May 25, 1976; and U.S. Pat. No. 4,387,090, Bolich, Jr., issued Jun. 7, 1983; and U.S. Patent 4,275,055, Nachtigal et al., issued June 23, 1981. A particularly preferred lubricant includes a mixture of polyvinylpyrrolidone and alkyl sulfosuccinate anionic surfactant.

10 [00022] The lubricating materials are preferably aqueous solutions, comprising from about 5% to about 80%, preferably from about 10% to about 30%, more preferably from about 10% to about 20% of the lubricant, depending on the lubricant. (All percentages herein are by weight, unless otherwise specified.) The lubricant material may include other 15 ingredients, such as stabilizers, thickening agents, pigments or colorants, dyes, organic solvents and cosolvents. Preferably the lubricating material contains an antiblocking agent, to facilitate rolling the casting aid by preventing lubricant layers from sticking together. Preferred antiblocking agents include particulates having a particle size of from about 10 microns to 20 about 400 microns, comprising mineral fillers such as talc and calcium carbonate, ceramic microspheres, aluminum or other oxide powders, polymers such as polystyrene, and glass microspheres.

25 [00023] The lubricating material may be coated on the substrate in any fashion that allows the lubricant to be transferred from the substrate to the glove when in use. Preferably, the lubricating material forms an essentially uniform layer covering substantially all of at least one surface of the substrate. In preferred embodiments wherein the substrate is a flexible sheet, the lubricating material can be coated on either or both of the major surfaces of the sheet. Preferably the lubricating material is coated at a level 30 of from about 0.002 to about 0.005 g/cm². More preferably, the lubricating material is coated at a level of from about 0.003 to about 0.004 g/cm². (As

referred to herein, "g/cm²" is the weight, in grams, of the lubricating material per square centimeter of substrate surface.)

[00024] The casting aid may be packaged, with one or more article per package or container, for storage before use. The invention further 5 provides a container comprising one or more of the casting aids. In the case of a volatile lubricant, the container may comprise a closed or, preferably sealed, package capable of preventing evaporation of the lubricating material, wherein the package contains one or more of the casting aids. Suitable packaging is well known in the art. For example, a package dispenser for 10 dispensing sheets of the invention may comprise a container having a cavity containing a plurality of the sheets. The container may have an opening on one end through which said sheets may be taken or pulled. The container may have one or more leak-proof layers, such as a hermetic seal. The seal may be made of a flexible material or of a deformable plastic coated foil or 15 uncoated foil. The container may be made of either a rigid or a flexible material, or a combination of rigid and flexible materials. For example, the container may be formed from a rigid plastic or semi-rigid plastic such as a polyethylene, polypropylene, polyethylene terephthalate, or from a more flexible material such as a composite film.

[00025] Multiple casting aids may be placed within the container 20 in random or ordered configurations. Accordingly, the sheets may be ordered in stacks or rolls in the containers. The container may contain, for example, a continuous web of material in compacted form having sheets connected in end-to-end relationship separated by scored lines or perforations, from which 25 the respective sheets can be readily dispensed, one at a time. Such a container may include a body containing the continuous web; a closure for the container; and a dispensing opening through which the web is withdrawn and a sheet of the web separated at the scored line or perforations. Preferably, as each sheet is pulled out and separated, the next sheet is exposed above 30 the dispensing opening. The web may be in the form of a roll, and the web may be drawn for dispensing from the center of the roll. Alternatively, the sheets may be stacked face-to-face in the container. In yet another

embodiment, the sheets may be partially overlapped or stacked as an interfolded array so that when one is withdrawn from the container, the next in the stack is presented in a graspable position.

Kits:

5 **[00026]** The present invention also provides kits for the formation of an orthopedic cast, comprising a casting material and a casting aid. As used herein, a "casting material" is any material which comprises a curable resin for use in making an orthopedic cast. The curable resin may be any of the kind known in the art, including water-curable, UV-curable, EB-curable, 10 heat-setting, and air-dry (oxygen-curing) materials. The casting material is preferably a curable-resin impregnated sheet (herein, a "tape"), preferably impregnated with a water-curable resin.

15 **[00027]** The curable resin of the casting material may be any curable resin that satisfies the functional requirements of an orthopedic cast. The resin-impregnated tape should be pliable before cure, but should upon cure become rigid and strong to support the loads and stresses to which the cast may be subjected by the activities of the patient. Such casts may be rigid, semi-rigid, or flexible, depending upon the nature of the condition to be treated.

20 **[00028]** Curing of the resin should take place fairly rapidly once curing has been initiated, preferably attaining weight bearing strength (for those casts that intended to be rigid) within about 30 minutes. The curable resin is selected from materials that preferably do not emit significant amounts of toxic by-products during curing that might be harmful to either the patient or the person applying the cast. The curable resin also is preferably non-irritating to the skin and should not generate an excessive amount of heat during curing that might cause discomfort or burns to the underlying skin.

25 **[00029]** The curable resin may cure by a variety of mechanisms. The cure reaction should not generate an amount of heat that would cause 30 discomfort or burns to exposed skin. Curable resin systems useful herein include catalyzed polyurethane prepolymers and water-reactive alkoxy silane terminated resins.

[00030] The curable resin is preferably a polyurethane prepolymer. Useful polyurethane prepolymers are described, for example, in U.S. Patents 4,131,114 Kirkpatrick et al., issued December 26, 1978; U.S. Patent 4,376,438, Straube et al., issued March 15, 1983; U.S. Patent 5 4,411,262 von Bonin et al., issued October 25, 1983; U.S. Patent 4,968,542 Gasper et al., issued November 6, 1990; and U.S. Patent 4,502,479 Garwood et al., issued March 5, 1986; incorporated by reference herein. The polyurethane prepolymer comprise, and may be prepared by reacting, one or more polyisocyanates with one or more polyols in an isocyanate/hydroxyl 10 equivalent ratio of from about 2:1 to about 12:1, preferably from about 3:1 to about 5:1. The polyisocyanate may be aliphatic, cycloaliphatic, or aromatic diisocyanates, triisocyanates, or tetraisocyanates, as well as biurets, isocyanurates, and similar oligomers of these. Examples of useful polyisocyanates include, without limitation, toluene diisocyanates (TDI), 15 including the 2,4 and 2,6 isomers and mixtures of these isomers; diphenylmethane diisocyanates (MDI), including the 4,4', 2,4', and 2,2' isomers and mixtures of these isomers; hydrogenated diphenylmethane diisocyanates, aromatic polyisocyanates derived from phosgenation of the condensation product of aniline and formaldehyde (polymeric MDI), 20 hexamethylene diisocyanate, isophorone diisocyanate, octamethylene diisocyanate, trimethylhexane diisocyanates, dodecamethylene diisocyanates, cyclopentane diisocyanate, cyclohexane diisocyanate, tetramethylxylene diisocyanate, and biurets, allophonates, isocyanurates, and substituted derivatives of these, such as carbodiimide-containing 25 polyisocyanates. Preferred among these are polymeric diphenylmethane diisocyanates (polymeric MDI's).

[00031] The polyisocyanate is reacted with at least one polyol. Examples of suitable polyols include, without limitation, polyether polyols, 30 polyester polyols including polycaprolactone polyols, and monomeric diols and triols such as 1,6-hexanediol. Preferred polyols include polyethylene oxide and polypropylene oxide diols and triols, polytetramethylene ether glycols, especially those having a molecular weight of from about 400 to

about 4000. Polyalkylene oxide polyols are available commercially, for example from BASF Corporation under the tradename Pluracol® and from Union Carbide Corporation under the tradenames Carbowax® and Polyox®.

[00032] Preferred polyols include polyethylene oxide and 5 polypropylene oxide diols and triols, having a molecular weight of at least about 2,000, preferably from about 2,000 to about 4,000, more preferably from about 3,000 to about 4,000. Preferably the polyol has a hydroxyl number of from about 28 to about 56, preferably from about 28 to about 46 more preferably from about 35 to about 40. As referred to herein, the 10 "hydroxyl number" is the number of milligrams, per gram of polyol, of potassium hydroxide having an acid neutralization capacity equal to the polyol. Preferred polyols include PPG 3025, having a molecular weight of about 3,000 and a hydroxyl number of from about 35 to about 40, sold by Lyondell Chemical Company, and QO Polymeg 3000, having a molecular 15 weight of from about 2,800 to about 3,000 and a hydroxyl number of from about 37 to about 40, sold by Great Lakes Chemical Corporation.

[00033] The curable resins of this invention have a level of free NCO of from about 4% to about 10%, preferably from about 7% to 10%, 20 preferably from about 7% to about 8%, more preferably about 7.5%. As referred to herein, the "level of free NCO" is the weight of the equivalents of NCO in excess of the equivalents of polyol in the prepolymer, as a percentage of the total weight of the prepolymer (weight of isocyanate plus the weight of the polyol). Preferred curable resins are disclosed in co-filed U.S. Patent Application Serial No. _____, "Orthopedic Casts with 25 Controlled Flexibility", Morris et al., incorporated by reference herein.

[00034] The prepolymer is preferably mixed with a catalyst. Preferred catalysts include tertiary amine catalysts such as tertiary alkanolamines, for example dimethylethanolamine and dimethylaminodiethyl ether; 2,2'-dimorpholinodialkylethers such as 2,2'-dimorpholinodiethyl ether 30 (DMDEE), available commercially from Texaco, Inc., as Thancat DMDEE; and 2,2'-dimorpholinodialkylethers, such as 4-[2-[methyl-2-(4-morpholinyl)ethoxy]-

ethyl]morpholine (MEMPE). The catalyst is preferably included in amounts of from about 0.1% to about 10% by weight of the impregnating resin mixture.

[00035] Preferably the casting material is substantially free of lubricating materials. As used herein, such "lubricating materials" are those disclosed in the art for admixture with the resin so as to make the resin slippery. Such lubricating materials are disclosed, for example, in U.S. Patents 4,667,661 and 4,774,937, incorporated by reference herein. As referred to here, casting materials that are "substantially free" of lubricating materials have no lubricating materials, or levels of lubricating materials that are sufficiently low so as to provide insignificant reduction in the tackiness of the resin. Preferably the casting materials contain less than 1% of such lubricating materials.

[00036] The curable resin mixture preferably has a viscosity that is low enough to allow the mixture to enter the pores of the tape, while the viscosity is high enough that a sufficient amount remains in the tape so that upon cure the tape is effectively hardened and the desired physical properties are obtained. The viscosity may be modified according to a variety of obvious means, such as by addition of low viscosity materials including, without limitation, organic solvents to reduce viscosity or by addition of thickening agents to increase viscosity. The optimum viscosity may be determined by straightforward testing. In a preferred embodiment of the invention, the viscosity of the curable resin mixture is from about 5000 to about 100,000 centipoise. The impregnating resin mixture may include other ingredients, such as stabilizers, thickening agents, antifoam agents, pigments, and colorants.

[00037] The tape is preferably an open-weave structure of a fibrous material. Examples of suitable porous material for the casting sheet include, without limitation, woven, knit, and non-woven fabrics of natural and/or synthetic fibers. Fabrics among those useful herein are described in U.S. Patent 3,686,725, Nisbet et al., issued August 29, 1972; U.S. Patent 3,787,272, Nisbet et al. issued January 22, 1974; U.S. Patent 4,323,061, Usukura, issued April 6, 1982; U.S. Patent 4,609,578, Reed, issued February

28, 1984; U.S. Patent 4,668,563, Buese et al., issued May 26, 1987; and U.S. Patent 4,745,912, McMurray, issued May 24, 1988; incorporated by reference herein. A preferred embodiment employs a knitted fabric that combines a high modulus fiber, such as a fiberglass, polyaramide, or carbon fiber, with an 5 elastomeric, highly extensible fiber, such as a natural rubber, spandex (a polyurethane), polyisoprene, polyethylene, polypropylene, polybutadiene, diene copolymers, acrylonitrile copolymers, EPM, or EPDM fiber. A particularly preferred tape is comprised of fiberglass and polypropylene, preferably comprising from about 8% to about 18%, more preferably from 10 about 10% to about 14%, of polypropylene.

[00038] The tape may be coated with a substance for modifying the fibers of the tape prior to impregnation with the curable resin mixture. The modifying substance preferably does not interfere with the impregnation or detrimentally affect the performance of the curable resin mixture. One 15 example of a modifying substance is a low modulus binder that may be applied to prevent or reduce fraying of cut ends of the substrate, as is disclosed in U.S. Patent 4,800,872, Buese et al., issued January 31, 1989 incorporated by reference herein.

[00039] The tape, when impregnated with the curable resin, 20 preferably has at least some flexibility. The impregnated casting material should have sufficient flexibility so that it can be molded about a limb without excessive pressure to support and/or protect the limb. The casting material is at least partially impregnated with a curable resin. Preferably, the resin mixture may flow into the capillary spaces between fibers of the fabric. Also 25 preferably, the curable resin mixture that is impregnated into the tape comprises from about 25% to about 60%, preferably from about 30% to about 50%, preferably from at 35% to about 48%, more preferably from about 40% to about 45%, by weight of the impregnated tape.

[00040] The specific composition of the casting aid need not 30 depend upon the curing mechanism of the tacky material. However, preferably the lubricating material is selected so as to avoid undesired

interactions with the resin mixture. The lubricating material preferably does not comprise a hydroxyl-functional lubricant.

[00041] The kits of this invention preferably comprise the casting aid and casting material in a suitable package. When the cast material is a thermoplastic, water-curable, or air-drying formulation, it is preferred for the casting material to be sealed in a compartment of the kit. The casting aid may be sealed in the same compartment as the casting material, or in a different compartment which may be sealed or unsealed. In a preferred embodiment, the casting material comprises a roll of sheets, around the circumference of which the casting aid is wrapped. Accordingly, such casting compositions of this invention comprise:

- (a) a casting material formed into a roll; and
- (b) a casting aid wrapped around the circumference of said roll.

In another preferred embodiment, the casting aid and the casting tape are folded into a single roll, the roll being then sealed inside of a compartment of the kit. In yet a further embodiment of the invention, the casting aid and the casting tape are separated by a third layer, all three layers being folded into a single roll and the roll being then sealed inside of a compartment of the kit.

[00042] The casting tape that is rolled into the roll of the kit may be from about 2.7 m (3 yards) to about 4.1 m (4.5 yards), preferably from about 3.6 m (4 yards) to about 3.8 m (4.2 yards) in length and from about 2.5 cm (1 inch) to about 25.4 cm (10 inches), preferably from about 2.5 cm (1 inch) to about 12.7 cm (5 inches), in width. Preferably the casting tape is wrapped around a cylindrical core, preferably cylindrical core described in U.S. Patent 5,984,884, Alvarez et al., issued November 16, 1999 (incorporated by reference herein). Such cylinders preferably have multiple "L"-shaped projections that extend radially outward from the core of the cylinders.

[00043] The sealing compartments may comprise a peelable layer over a shell of a material inert toward both the lubricant-impregnated substrate and the water-curable resin-impregnated cast sheet. Alternatively,

the kit may comprise foil, foil-lined, plastic, or metallized plastic pouches or compartments.

[00044] The kit may further include gloves suitable for wearing during the cast molding process. Suitable gloves that may be used to handle 5 the tacky material include gloves made from vinyl (such as polyvinyl chloride), latex, butyl rubber, or other such elastomeric materials. The gloves should be substantially nonporous to the lubricant so that the lubricant is not absorbed by the glove but instead remains, at least for the most part, on the surface of the glove.

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Methods of Making Casts:

[00045] The present invention also provides methods for forming an orthopedic cast by hand around a body member of a human or other animal subject, using a casting material, a casting aid, and a glove. Such 15 methods comprise the steps of:

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- (1) transferring the lubricating material to a surface of the glove;
- (2) applying the casting material to a body member using the glove; and
- (3) allowing the casting material to harden to form an orthopedic cast.

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[00046] The step of transferring the lubricating material to the glove is performed by contacting a surface of the glove with the casting aid, for example by rubbing the casting aid on the desired surface of the glove one or more times. One or two gloves may be used during the methods of this invention. One or both of the casting aid or the glove may optionally be wetted with water or immersed in water before transferring the lubricant to the glove, and this step may be preferred when the lubricant is water soluble or water dispersible. In some cases, the casting aid may be immersed in water or wetted before being used one or more times to deliver lubricant as needed 30 to the gloves.

[00047] In the step of applying the casting material to a body member, the casting tape is wrapped about the subject's body member, or

otherwise applied in multiple adjacent layers, using the glove(s) to which the lubricant has been applied by means of the casting aid. The application is assisted by the reduction in tackiness of the substrate relative to the gloves without reducing significantly the tackiness of the cast substrate relative to itself. When the desired amount of casting material has been wrapped around the body member, it is often desirable to further mold the wrapped cast material about the body member. Lubricant may be re-applied from the casting aid to the gloves before and during molding the wrapped cast material as desired.

10 [00048] An important aspect of many of the preferred embodiments of the present invention is the ability of the person applying the casting material to control the amount of lubricant applied to the gloves during molding of the cast, as well as the timing of the application. If the gloves begin to stick to the cast tape during the step of applying the tape, lubricant 15 may be reapplied to the glove(s) by wiping the glove(s) with the casting aid. Accordingly, preferred methods of this invention comprise an additional step of transferring the lubricating material to a surface of the glove performed during the step of applying the casting material to the body member.

20 [00049] It is also sometimes desirable to use less lubricant prior to and during application of the casting material, so that the tape and packaging can be easily handled during the wrapping step. This can be accomplished by limiting the transfer of lubricant from the casting aid to the glove(s).

25 [00050] After application of the casting material is completed, the casting material is allowed to fully harden to form a cast about the wrapped limb. In one embodiment of the invention, the casting material comprises a thermoplastic composition that hardens on cooling. In a preferred embodiment of the invention, the casting material comprises a curable composition-impregnated sheet, particularly a water-reactive or water-30 activated curable composition. In the case of a water-reactive or water-activated curable composition, the casting material is immersed in water or otherwise wetted with water prior to applying the casting material around the

body member. After the casting material is applied, preferably by wrapping and molding about the body member, the curable composition is cured to form the finished cast.

5 [00051] The following non-limiting examples illustrate the compositions and methods of the present invention.

Example 1

10 [00052] A casting material is made comprising a casting tape of fiberglass with approximately 10% polypropylene fiber, about 3 inches (7.6 cm) wide, 4 yards (3.7 m) long, and 1 mm (4 mil) thick. The tape has approximately 25% stretch and a mesh size of approximately 43.4 holes/cm² (280 holes/inch²). A 230-meter (250-yard) roll of casting tape is partially fused by applying a narrow band of heat at approximately 315°C (600°F), at 3.7-meter (4-yard) intervals. The roll is then dried at approximately 110°C (230°F) for approximately 4 hours.

15 [00053] A resin composition is made as having the following composition:

<u>Material</u>	<u>% (by weight)</u>
Isonate TM 2143L ¹	58.0
PPG 725 ²	38.0
dimorpholinodiethyl ether	2.4
benzoyl chloride	0.1
silicone 200 fluid ³	0.3

¹ diphenylmethane diisocyanate resin, sold by Dow Chemical, Midland, Michigan

20 ² a polypropylene glycol, sold by Arco Chemical Co., Charlotte, North Carolina

³ 35,000 centipoise polydimethylsiloxane, sold by Dow Corning Corp., Midland, Michigan

25 [00054] The composition is made by admixture of the components, and heated with stirring to approximately 71°C (160°F) for

approximately 4 hours. The roll of casting tape is removed from the drying oven and passed through the resin. After passing through the resin, the tape is squeezed through rollers to remove excess resin, so that the resin is impregnated at a level of about 42% by weight of the final impregnated tape.

5 The tape is then cut where fused, to form individual strips of tape that are 3.7 m (4 yards) in length. An individual tape is then wound on a cylindrical core described in U.S. Patent 5,984,884, Alvarez et al., issued November 16, 1999 (incorporated by reference herein).

[00055] A casting aid according to this invention is made having
10 the following lubricating material composition.

<u>Material</u>	<u>% (by weight)</u>
carboxymethylcellulose	13.6
sodium dihexyl sulfosuccinate	9.5
talc	20.0
water	56.9

[00056] The lubricating material is coated on a sheet of surface-oxidized Mylar® polyethylene film approximately 10.2 cm wide (4 inches), 20.3 cm (8 inches) long, and 0.8 mm (3 mil) thick. The coated film is then dried in an oven, resulting in a coating layer approximately 0.34 mm (1.5 mils) thick. The casting aid is then wrapped around the roll of impregnated casting sheet. The wrapped roll is sealed in a foil pouch under nitrogen, along with a desiccant pouch, to make a kit according to this invention.

[00057] The sealed pouch is later opened and the orthopedic casting article is removed. Using latex gloves, the roll of casting material covered with the casting aid is placed in water and squeezed twice while underwater. The roll is then taken out of the water and squeezed to remove excess amounts of water. The covered roll is used to wet both gloves being worn by rolling it between the palm and wiping both palm, transferring lubricating material from the casting aid to the gloves. The casting aid is then laid aside and the wrapping process begun.

[00058] The casting sheet is next unrolled while wrapping the sheet around the limb of a human subject to form a cast. The lubricated gloves prevent the resin from the tape from sticking to the gloves and allow the hands to move freely in the molding of the cast. The casting aid is used 5 to re-apply more lubricant to coat the palms of the gloves during the wrapping process.

Example 2

[00059] A casting material is then made comprising a casting tape of fiberglass with approximately 12% polypropylene fiber, about 10 cm (4 10 inches) wide and 3.7 m (4 yards) long and 0.9 mm (0.36 inches) thick. The tape has approximately 25% stretch and a mesh size of approximately 40.3 holes/cm² (260 holes/inch²). The tape is impregnated with the following mixture:

<u>Material</u>	<u>% (by weight)</u>
Isonate TM 2143L ¹	30.8
PPG 3025 ²	64.4
dimorpholinodiethyl ether	3.9
benzoyl chloride	0.1
silicone	0.2
butylated hydroxytoluene	0.2
titanium dioxide	0.4

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¹ modified diphenylmethane diisocyanate resin, sold by Dow Chemical, Midland, Michigan

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² a polypropylene glycol, having a hydroxyl number of approximately 37, sold by Lyondell Chemical Company, South Charleston, West Virginia

³ 35,000 centipoise polydimethylsiloxane, sold by Dow Corning Corp., Midland, Michigan

[00060] The tape is made, rolled and impregnated with resin as described in Example 1.

[00061] A casting aid according to this invention is made, having the following lubricating material composition.

<u>Material</u>	<u>% (by weight)</u>
PVP K-90 ¹	64.0
Aerosol OT-75% ²	3.3
W610 Ceramic	3.7
Zeeospheres ³	
water	29.0

5

¹ solution containing approximately 20% polyvinylpyrrolidone in water, sold by BASF

² solution containing approximately 75% sodium dioctyl sulfosuccinate in ethanol/water, sold by Cytec Industries

10 ³ ceramic microspheres, sold by 3M

[00062] The lubricating material is coated on a sheet of surface-oxidized polyethylene approximately 13 cm (5 inches) wide, 20 cm (8 inches) long, and 0.5 mm (2 mil) thick. The casting aid is then wrapped around the roll of impregnated casting sheet. The wrapped roll is sealed in a foil pouch under nitrogen, to make a kit according to this invention.

[00063] The examples and other embodiments described herein are exemplary and not intended to be limiting in describing the full scope of compositions and methods of this invention. Equivalent changes, modifications and variations of specific embodiments, materials, compositions and methods may be made with substantially similar results.

What is claimed is:

1. A casting aid, comprising:
 - (a) a resin-impermeable substrate; and
 - (b) a lubricating material,
wherein said lubricating material is coated on at least one surface of
said substrate.
2. A casting aid according to Claim 1, wherein said substrate is a flexible
sheet.
- 10 3. A casting aid according to Claim 2, wherein said substrate is a non-
porous flexible sheet comprising a thermoplastic polymer.
4. A casting aid according to Claim 3, wherein said thermoplastic polymer
is selected from the group consisting of polyesters, polyolefins, and
mixtures thereof.
- 15 5. A casting aid according to Claim 4, wherein said hydrophobic polymer
is polyester.
6. A casting aid according to Claim 2, wherein said flexible sheet is from
about 0.25 mm to about 1.0 mm in thickness.
7. A casting aid according to Claim 2 wherein said flexible sheet is from
20 about 5 cm to about 13 cm in width, and from about 15 cm to about 25
cm in length.
8. A casting aid according to Claim 1, wherein said lubricating material
comprises a lubricant selected from the group consisting of
hydroxyethyl cellulose, carboxymethylcellulose, polyvinylpyrrolidone,
25 polyvinyl alcohol, polyacrylic acid salts, polyethylene oxide polymers,
and mixtures thereof.
9. A casting aid according to Claim 8, wherein said lubricant is
polyvinylpyrrolidone.
10. A casting aid according to Claim 8, wherein said substrate is coated
30 with said lubricating material at a level of from about 0.002 to about
0.005 g/cm².

11. A casting aid according to Claim 1, wherein said lubricating material additionally comprises a blocking agent.
12. A casting aid according to Claim 2, wherein said lubricating material is coated on one major surface of said flexible sheet.
- 5 13. A kit for the formation of an orthopedic cast, comprising:
 - (a) a casting material comprising a tape impregnated with an isocyanate functional prepolymer; and
 - (b) a casting aid according to Claim 1.
14. A kit for the formation of an orthopedic cast, comprising:
 - (a) a casting material; and
 - (b) a casting aid comprising a resin-impermeable substrate and a lubricating material coated on a surface of said substrate.
- 10 15. A kit according to Claim 14, wherein said casting material comprises a tape impregnated with a water-activated resin composition.
- 15 16. A kit according to Claim 15, wherein said resin composition is selected from the group consisting of alkoxy silane terminated polyurethane oligomers, and isocyanate-functional pre-polymers.
17. A kit according to Claim 16, wherein said resin composition is an isocyanate-functional prepolymer.
- 20 18. A kit according to Claim 17, wherein said prepolymer comprises an isocyanate and a polyol.
19. A kit according to Claim 18, wherein said polyol has a molecular weight greater than about 2,000.
20. A kit according to Claim 19, wherein said polyol has a hydroxyl number of from about 28 to about 56.
- 25 21. A kit according to Claim 17, wherein said resin composition is essentially free of a lubricant.
22. A kit according to Claim 15, wherein said tape comprises fibers selected from the group consisting of fiberglass, polyethylene, polypropylene, polyacrylonitrile copolymers and mixtures thereof.
- 30 23. A kit according to Claim 22, wherein said sheet comprises a mixture of fiberglass and polypropylene fibers.

24. A kit according to Claim 14, wherein said substrate is a non-porous flexible sheet comprising a thermoplastic polymer.
25. A kit according to Claim 24, wherein said thermoplastic polymer is polyester.
- 5 26. A kit according to Claim 24, wherein said flexible sheet is from about 0.25 mm to about 1.0 mm in thickness, and is from about 5 cm to about 13 cm in width, and from about 15 cm to about 25 cm in length.
- 10 27. A kit according to Claim 24, wherein said lubricating material comprises a lubricant selected from the group consisting of hydroxyethyl cellulose, carboxymethylcellulose, polyvinylpyrrolidone, polyvinyl alcohol, polyacrylic acid salts, polyethylene oxide polymers, and mixtures thereof.
- 15 28. A kit according to Claim 27, wherein said lubricant is polyvinylpyrrolidone
29. A kit according to Claim 14 additionally comprising a glove.
30. A kit according to Claim 24, wherein said tape comprises two or more tapes formed into a roll.
31. A kit according to Claim 24, wherein said roll is covered, at least in part, by said casting aid.
- 20 32. A casting composition comprising:
 - (a) a casting material formed into a roll; and
 - (b) a casting aid wrapped around the circumference of said roll.
33. A casting composition according to Claim 32, wherein said casting material comprises a tape impregnated with a thermoplastic composition comprising an isocyanate prepolymer.
- 25 34. A method of forming an orthopedic cast by hand around a body member of a human or other animal subject using a casting aid according to Claim 1.
35. A method of forming an orthopedic cast by hand around a body member of a human or other animal subject, using:
 - (a) a casting material;

- (b) a casting aid, comprising a resin-impermeable substrate and a lubricating material coated on said substrate; and
- (c) a glove,
comprising the steps of:
 - 5 (1) transferring said lubricating material to a surface of said glove;
 - (2) applying said casting material to said body member using said glove; and
 - (3) allowing said casting material to harden to form said orthopedic cast.

10 36. A method according to Claim 35, wherein said casting material comprises a tape impregnated with a resin composition.

37. A method according to Claim 36, wherein said resin composition is water-activated.

38. A method according to Claim 37, wherein said resin composition is selected from the group consisting of alkoxy silane-terminated polyurethane oligomers, and isocyanate-functional pre-polymers.

15 39. A method according to Claim 38, wherein said resin composition is an isocyanate-functional prepolymer.

40. A method according to Claim 39, wherein said resin composition comprises an isocyanate and a polyol.

20 41. A method according to Claim 40, wherein said polyol has a hydroxy equivalent weight of greater than about 2,000.

42. A method according to Claim 41, wherein said polyol has a hydroxyl number of from about 28 to about 56.

25 43. A method according to Claim 40, wherein said resin composition is essentially free of a lubricant.

44. A method according to Claim 36, wherein said tape comprises a fibers selected from the group consisting of fiberglass, polyethylene, polypropylene, polyacrylonitrile copolymers and mixtures thereof.

30 45. A method according to Claim 44, wherein said tape comprises a mixture of fiberglass and polypropylene fibers.

46. A method according to Claim 35, wherein said substrate is a non-porous flexible sheet comprising a thermoplastic polymer.
47. A method according to Claim 46, wherein said thermoplastic polymer is polyester.
- 5 48. A method according to Claim 47, wherein said flexible sheet is from about 0.25 mm to about 1.0 mm in thickness, and is from about 5 cm to about 13 cm in width, and from about 15 cm to about 25 cm in length.
49. A method according to Claim 46, wherein said lubricating material
- 10 comprises a lubricant selected from the group consisting of hydroxyethyl cellulose, carboxymethylcellulose, polyvinylpyrrolidone, polyvinyl alcohol, polyacrylic acid salts, polyethylene oxide polymers, and mixtures thereof.
50. A method according to Claim 49, wherein said lubricant is
- 15 polyvinylpyrrolidone
51. A method according to Claim 35, additionally comprising a step of activating said casting material by immersing said casting material in water.
52. A method according to Claim 51, wherein said casting material is
- 20 immersed in water while at least partially covered by said casting aid.
53. A method according to Claim 35, comprising an additional step of transferring said lubricating material to a surface of said glove performed during said step of applying said casting material to said body member using said glove.

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